



# ***MTC Industries, Inc.***

Pharmaceuticals, Nutraceuticals and Biochemicals

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VL/FDA

From,

MTC Industries Inc.  
299 East shore road, suite 207  
Great Neck, NY 11023.  
Tel: 516 466 5198. Fax: 516 466 5185.

To,

Vickey Lutwak  
Division Of New Dietary Supplements  
FDA, USA.

**Subject: Statement of Confirmation.**

1. The new dietary ingredient contained in our dietary supplement formula is  
L- Arginine alpha Ketoglutarate ( 2:1 ) .
2. According to Section 201FF, for new dietary ingredient, we want the  
L-Arginine alpha ketoglutarate (2:1) to be in the aminoacid category.





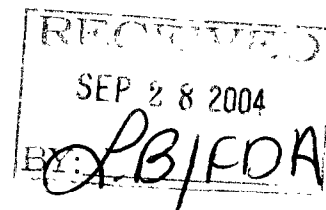
# ***MTC Industries, Inc.***

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September 27, 2004

To: Linda Pellicore (HFS-810)  
5100 Paint Branch Pkwy  
College Park, MD 20740  
Tel: (301) 436-1448

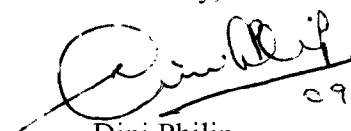
From: Dini Philip  
MTC Industries, Inc.  
299 East Shore Road, Suite 207  
Great Neck, NY 11023  
Tel: (516) 466-5198  
[dini@mtcindustries.com](mailto:dini@mtcindustries.com)



Dear Linda,

Based on our conversation last month, please find enclosed the documents for the new dietary ingredient pre-market approval for L-Arginine alpha-ketoglutarate. We're submitting the original and two copies for your kind perusal. Please acknowledge receipt and grant us pre-market approval at your earliest convenience. If you have any questions or comments regarding this matter, feel free to contact us via email or phone.

Sincerely,

  
Dini Philip  
Sales Manager

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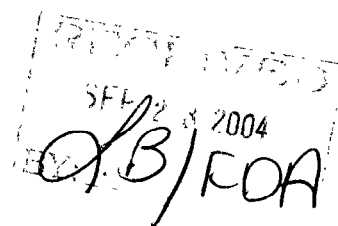
## APPLICATION FOR NEW DIETARY INGREDIENT PREMARKET NOTIFICATION

### 3. Manufacturers Name and Address:

Molecules Technology (Nantong) Co. Ltd.  
# 15 Fuxing Road, Nantong City  
Hi- Tech Park, Jiangsu Province,  
China 201203.

### Distributors Name and Address:

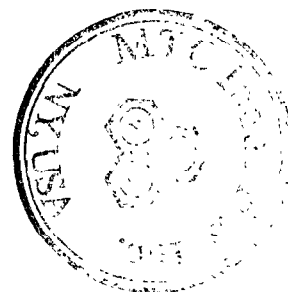
MTC Industries Inc.  
299 East Shore Road, Suite 207  
Great Neck, NY 11023.  
Tel: 516 466 5198 Fax: 516 466 5185.



### 4. Name Of The New Ingredient / Trade Name:

L- Arginine alpha ketoglutarate (2:1) or (1:1)

Trade Names: Arginine alpha keto glutarate, Arginine AKG, AAKG.



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3.

## LEVEL OF THE INGREDIENT IN THE DIET SUPPLEMENT & CONDITIONS OF USE RECOMMENDED ON THE LABEL.

1. 1,000 mg of Arginine alpha-ketoglutarate per tablet.

2. Suggested use:

Adult Men: Take 2 tablets once in the morning before breakfast and 2 tablets in the afternoon on an empty stomach. Adult women: Take 1 tablet in the morning before breakfast and 1 tablet in the afternoon on an empty stomach. Refer to chart for dosage by weight. Do not use if under 18 years of age.

Gender/lbs	Min.AM dose	Min.PM dose	Max.AM dose	Max.PM dose
Women <125	1	1	2	2
Women >125	2	2	3	3
Men <200	2	2	3	3
Men >200	3	3	4	4

For best results:

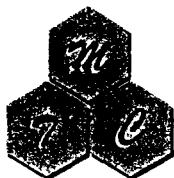
Drink at least 64 ounces of water daily.

Maintain your carbohydrate intake above 40% of your total daily caloric intake.

Do not consume foods at least 30 minutes before or 30 minutes after taking this supplement.

Do not take servings after 3:00 pm. Although this supplement contains no stimulants of any kind, it may keep you awake.

ACCC



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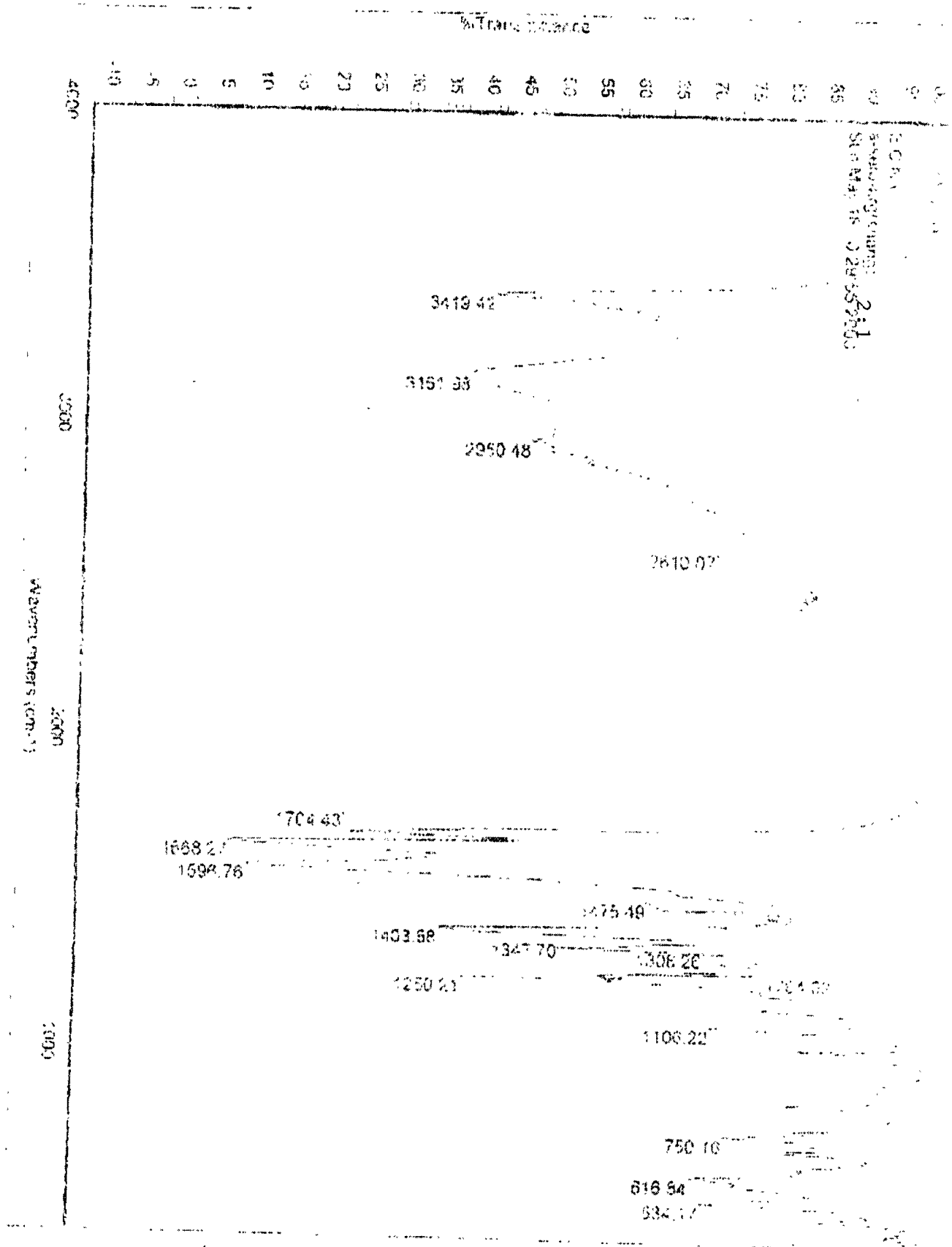
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Flow Chart for L-Arginine AKG: MANUFACTURING AND PROCESSING

REDACTED IN ITS  
ENTIRETY  
CONTAINS  
TRADE SECRET  
CONFIDENTIAL  
COMMERICAL  
INFORMATION

CONF

IDENTITY TESTING BY IR - AAKG 2:1

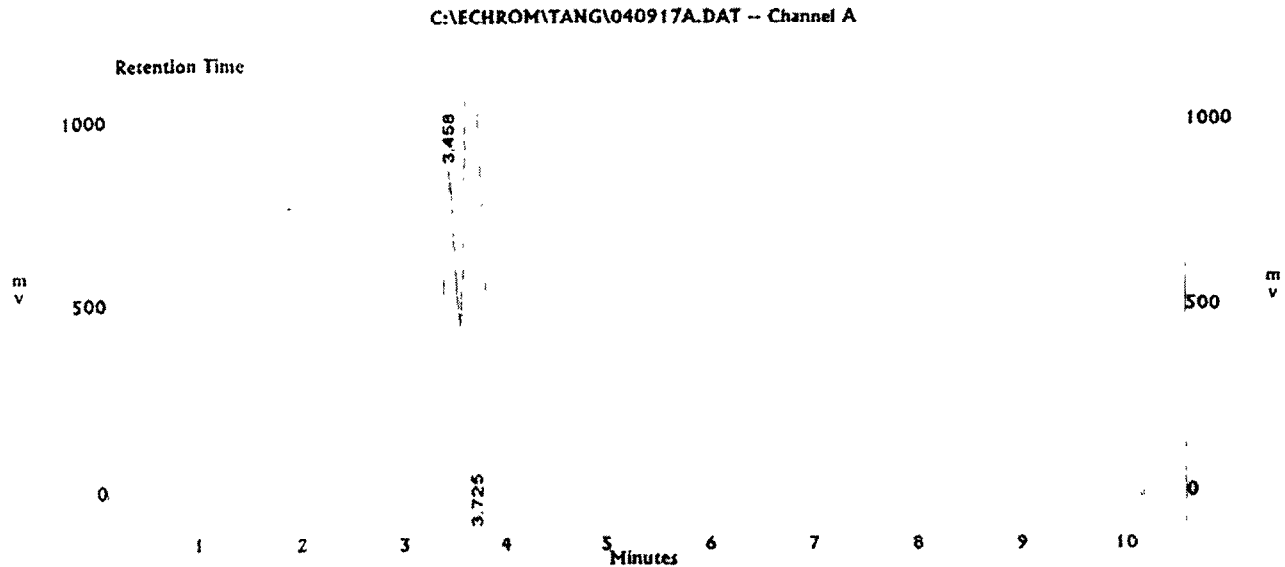


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# HPLC REPORT FOR L-ARGININE ALPHA KETO GLUTARATE 2:1

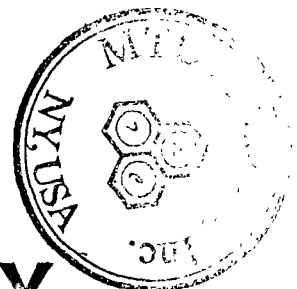
Arg :  $\alpha$ -keto = 2 1

File : C:\ECHROM\TANG\040917A.DAT  
 Method : C:\ECHROM\Untitled.met  
 Sample ID : 07  
 User : Czp



A Method

1	3.46	7498786	30.324
2	3.72	17229746	69.676
Totals :		24728532	100.000



CCFY



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## L - ARGININE ALPHA KETOGLUTARATE

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HISTORY OF USE AND EVIDENCE OF SAFETY WITH REFERENCES TO:

- a) Toxicity and Safety
- b) Clinical Studies.

Detailed Product Information on:

1. Nytric EFX by All American Pharmaceutical & Natural Foods
2. NitroGenX by Pharmagenx
3. NOx2 by Pinnacle
4. Nitrox by Sci Fit Nutrition.

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